CatalYm Advances Visugromab into Phase 2/3 Development for Cancer Cachexia with First Patient Dosed

- **Trial will evaluate visugromab's potential to reverse cancer-associated weight loss and muscle wasting by targeting GDF-15 in patients with advanced solid tumors**
- **Fourth Phase 2b study of visugromab broadens CatalYm's late-stage development program into severe cancer-associated condition impacting treatment outcomes**

Munich, Germany and San Francisco, USA, April 16, 2026 – CatalYm today announced that the first patient has been dosed in the Phase 2/3 VINCIT trial (Visugromab IN Cachexia International Trial, NCT07112196). The global study is evaluating the company's lead anti-GDF-15 antibody visugromab in patients with cancer-associated cachexia.

The randomized, double-blind, placebo-controlled Phase 2/3 trial will enroll about 518 patients with cachexia associated with a range of advanced cancers, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC), and other solid tumors.

Cachexia is a severe metabolic condition marked by involuntary weight loss, muscle wasting, and impaired treatment tolerance. In some types of cancer, it can affect up to 70% of patients and is responsible for 20-40% of cancer-related deaths[1]. Elevated GDF-15 levels are known to play a central role in the development of cachexia. Despite a high unmet medical need, there are currently no approved pharmacological treatments available.

"Cachexia remains one of the most debilitating and under-addressed complications in oncology," said **Sujata Rao, MD, Chief Medical Officer at CatalYm**. "Following the promising weight gain data observed in our earlier trial and growing evidence of GDF-15's role in metabolic wasting, this trial is a critical step in establishing visugromab as a novel therapeutic option for patients with advanced cancers."

"The data guiding this trial show that GDF-15 is more than a bystander in cancer progression. It plays a central role in both immune resistance and metabolic decline," said **Scott Clarke, Chief Executive Officer at CatalYm**. "By targeting GDF-15, visugromab has the potential to open a new therapeutic path for patients whose treatment outcomes are severely impacted by cachexia."

The VINCIT trial is an adaptive Phase 2/3 study to evaluate the efficacy and safety of visugromab in reversing cachexia. In Part 1, participants are randomized to receive one of three visugromab dose levels or placebo every four weeks for 12 weeks. Based on interim analyses, a recommended dose will be selected for Part 2, which will randomize patients 2:1 to visugromab or placebo for up to 52 weeks. The trial will include clinical sites across the globe. Primary endpoints include changes in body weight and appetite over 12 weeks. Secondary endpoints assess muscle mass and function, physical activity, tumor response,

overall survival, patient-reported quality of life, and safety. The study also includes exploratory pharmacodynamic and biomarker assessments.

Visugromab is a humanized, monoclonal antibody that targets Growth Differentiation Factor-15 (GDF-15), a tumor-derived cytokine known to drive immune suppression and cachexia. In the exploratory Phase 1/2a GDFATHER trial (NCT04725474), visugromab in combination with PD-1 inhibitor nivolumab demonstrated deep and durable anti-tumor activity as well as a favorable safety profile in patients with relapsed or refractory NSCLC, hepatocellular carcinoma (HCC) and urothelial cancer (UC). The trial also provided early clinical evidence for visugromab's potential to alleviate cancer cachexia, including meaningful weight gain in the subset of patients with moderate or severe weight loss at trial entry. These findings support visugromab's dual potential to maintain or restore immune function and counteract cancer cachexia.

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About cancer cachexia and GDF-15

Cancer cachexia is a complex and debilitating syndrome that affects up to 70% of patients with advanced cancer[1]. The condition is closely linked to elevated GDF-15 levels, which drive severe and progressive weight loss, muscle wasting, reduced appetite, and metabolic disturbances through activation of the GFRAL receptor in the brainstem. Unlike starvation, cachexia cannot be fully reversed with nutritional support alone, as it is driven by a combination of systemic inflammation, tumor-derived factors, and metabolic dysregulation. This condition significantly diminishes the quality of life for cancer patients and severely impacts their ability to tolerate and respond to treatment, often leading to poorer outcomes and increased mortality.

About Visugromab

Visugromab is a monoclonal antibody that neutralizes Growth Differentiation Factor-15 (GDF-15), a locally acting immunosuppressant produced by tumors which fosters immunotherapy resistance and drives cachexia in people with cancer. Neutralizing GDF-15 with visugromab reverses key cancer resistance mechanisms to reinstate an efficient anti-tumor response by re-enabling immune cell activation, proliferation and induction of interferon-γ. In addition, visugromab also mitigates cancer cachexia, a severe condition affecting a significant number of advanced cancer patients by inhibiting the activation of the GFRAL pathway in the brainstem, a key driver of weight loss and appetite suppression in cancer patients.

About CatalYm

CatalYm is developing visugromab, a first-in-class anti-GDF-15 antibody, in solid tumors and cachexia. In its first-in-human Phase 1/2a study, visugromab demonstrated deep and durable anti-tumor efficacy with long-lasting objective responses in relapsed and checkpoint refractory metastatic solid tumor patients in combination with anti-PD-1 treatment. In addition, data from the same study demonstrated that visugromab can significantly

[1] Fearon K. et al. *Lancet Oncol*. 2011;12(8):489–495.

counteract the effects of cachexia in these patients. This data was published in *Nature* and presented at the International Conference on Sarcopenia, Cachexia & Wasting Disorders. CatalYm is now advancing visugromab into multiple Phase 2b studies including first-line metastatic non-squamous NSCLC (NCT07098988), second-line metastatic non-squamous NSCLC (NCT07246863), second-line hepatocellular carcinoma (NCT07219459) and cachexia (NCT07112196).

Founded in 2016 and based in Munich, Germany and San Francisco, USA, CatalYm is backed by leading international investors including Canaan Partners, Omega Funds, Bioqube Ventures, Forbion, Jeito Capital, Brandon Capital, Gilde Healthcare, Novartis Venture Fund, Vesalius, Bayern Kapital, BioGeneration Ventures, and Coparion.

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